K080198

p1 of 2

TSO

510(k) Summary of Safety and Effectiveness

Applicant's Name and Address
TSO_3 Inc.
2505, avenue Dalton
Québec (Quebec) Canada G1P 3S5

MAY 30 2008

Contact Person, Telephone, FAX
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Submission Date
January 23, 2008

Trade Name
TSO_3 Ozone Sterilization Wrap

Common Name
CSR Wrap or Sterilization Wrap

Classification Name
Wrap, Sterilization
Class II (as per 21CFR, part 880.6850 equivalent device)

Legally Marketed Equivalent Device Name(s)
Suprashield Express® Sterilization Wrap (K990300)

TSO

Description of Device

The *TSO_3 Ozone Sterilization Wrap* is a single-use, non-sterile device. It is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device, and also to maintain sterility of the enclosed device until used. This wrap is intended for use in the TSO_3 Ozone Sterilization process.

The *TSO_3 Ozone Sterilization Wrap* is a 2 layer laminate consisting of an ePTFE membrane and a 100% Polyethylene/Polyester (PE/PET) bi-component nonwoven backer.

Effectiveness

Sterilization performance studies and shelf-life sterility tests were conducted and all acceptance criteria were met.

Safety

The material used in the composition of the *TSO_3 Ozone Sterilization Wrap* (ePTFE/PE/PET) was evaluated and tested as required in ISO 10993 standard, part 1. These materials were evaluated for skin irritation, cytotoxicity testing, and sensitization. Results were submitted as part of the 510(k) submission for the TSO_3 *125L* Ozone Sterilizer (K020875). All acceptance criteria established in the applicable portions of the standards were met.

A skin irritation test was performed by an independent laboratory to demonstrate that the final product does not induce any biocompatibility hazard. Refer to Annex V for test protocol and results (test report).

Substantial Equivalence

The TSO_3 Sterilization Wrap is substantially equivalent to the Suprashield Express® Sterilization Wrap (K990300) in that the:

- Intended use is the same
- Performance attributes are the same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2008

TSO3 Incorporated
C/O Mr. Charles O. Hancock
Regulatory Affairs Consultant
Charles O. Hancock Associates, Incorporated
33 Black Watch Trail
Fairport, New York 14450

Re: K080198
Trade/Device Name: TSO_3 Ozone Sterilization Wrap
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: May 13, 2008
Received: May 13, 2008

Dear Mr. Hancock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

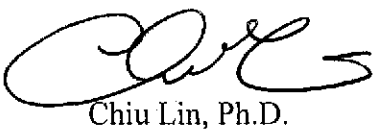
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K080198**

Device Name: **TSO_3 Ozone Sterilization Wrap**

Indications For Use:

The *TSO_3 Ozone Sterilization Wrap* is a single-use, non-sterile device. It is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device, and also to maintain sterility of the enclosed device until used. This wrap is intended for use with TSO_3 Ozone Sterilization process.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080198 Page 1 of _____